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Attorneys for Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PFIZER INC., PHARMACIA & UPJOHN COMPANY LLC, and PFIZER HEALTH AB, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	**Civil Action No. 07-11198-LTS(KNF)**

PFIZER'S REPLY TO THE ANSWER AND COUNTERCLAIMS OF TEVA PHARMACEUTICALS USA, INC.

Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB (collectively, "Pfizer"), by their attorneys White & Case LLP, for their Reply to the Answer and Counterclaims of Defendant and Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva"), allege:

Paragraphs 1 through 30 of Teva's Answer and Counterclaims respond to paragraphs 1 through 30 of Pfizer's Complaint in this action. Paragraphs 31 through 86 of Teva's Answer and Counterclaims set forth Teva's Affirmative Defenses. Accordingly,

paragraphs 1 through 86 of Teva's Answer and Counterclaims do not require a response. To the extent that a response is required, Pfizer denies the allegations of paragraphs 1 through 86.

REPLY TO COUNTERCLAIMS

Pfizer responds to the numbered allegations of Teva's Counterclaims as follows.

1. Pfizer admits the allegations of paragraph 1.

2. Pfizer admits the allegations of paragraph 2.

3. Pfizer admits the allegations of paragraph 3.

4. Pfizer admits that Pfizer Health AB is a company organized and existing under the laws of Sweden, having a place of business at SE-112 87, Stockholm, Sweden. Pfizer also admits that Pfizer Inc. is the ultimate parent of Pfizer Health AB. Pfizer neither admits nor denies that which comprises the remainder of paragraph 4.

5. Pfizer neither admits nor denies the allegations of paragraph 5, as only conclusions of law are set forth therein.

6. Pfizer neither admits nor denies the allegations of paragraph 6, as only conclusions of law are set forth therein.

7. Pfizer admits that it filed the Complaint in this action. Pfizer neither admits nor denies the remaining allegations of paragraph 7, as they set forth only conclusions of law.

8. Pfizer neither admits nor denies the allegations of paragraph 8, as only conclusions of law are set forth therein.

9. Pfizer admits the allegations of paragraph 9.

10. Pfizer admits that, by letter to Pfizer, dated October 29, 2007, Teva disclosed the submission to the United States Food and Drug Administration of Abbreviated New Drug Application No. 79-141, and that, by such communication, Teva alleged that it had made a

certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) concerning U.S. Patent No. 5,382,600 (the "'600 patent"), U.S. Patent No. 6,630,162 (the "'162 patent"), and U.S. Patent No. 6,770,295 (the "'295 patent"). Pfizer is without knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 10.

11. Pfizer denies the allegations of paragraph 11.

12. Pfizer denies the allegations of paragraph 12.

13. Pfizer admits that Teva realleges paragraphs 1 through 12. Pfizer hereby realleges and incorporates by reference the averments in paragraphs 1 through 12 of this Reply.

14. Pfizer neither admits nor denies the allegations of paragraph 14, as only conclusions of law are set forth therein.

15. Pfizer denies the allegations of paragraph 15.

16. Pfizer admits that Teva realleges paragraphs 1 through 12. Pfizer hereby realleges and incorporates by reference the averments in paragraphs 1 through 12 of this Reply.

17. Pfizer neither admits nor denies the allegations of paragraph 17, as only conclusions of law are set forth therein.

18. Pfizer denies the allegations of paragraph 18.

19. Pfizer admits that Teva realleges paragraphs 1 through 12. Pfizer hereby realleges and incorporates by reference the averments in paragraphs 1 through 12 of this Reply.

20. Pfizer neither admits nor denies the allegations of paragraph 20, as only conclusions of law are set forth therein.

21. Pfizer denies the allegations of paragraph 21.

22. Pfizer admits that Teva realleges paragraphs 1 through 12. Pfizer hereby realleges and incorporates by reference the averments in paragraphs 1 through 12 of this Reply.

23. Pfizer neither admits nor denies the allegations of paragraph 23, as only conclusions of law are set forth therein.

24. Pfizer denies the allegations of paragraph 24.

25. Pfizer admits that Teva realleges paragraphs 1 through 12. Pfizer hereby realleges and incorporates by reference the averments in paragraphs 1 through 12 of this Reply.

26. Pfizer neither admits nor denies the allegations of paragraph 26, as only conclusions of law are set forth therein.

27. Pfizer denies the allegations of paragraph 27.

28. Pfizer admits that Teva realleges paragraphs 1 through 12. Pfizer hereby realleges and incorporates by reference the averments in paragraphs 1 through 12 of this Reply.

29. To the extent that by "this matter," Teva refers to this Civil Action, Pfizer admits the allegations of paragraph 29.

30. Pfizer admits that, pursuant to 37 C.F.R. § 1.56, as interpreted by the U.S. Court of Appeals for the Federal Circuit and other courts, an "individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [United States Patent and Trademark] Office." Pfizer also admits that Nils A. Jönsson, Bengt A. Sparf, Lembit Mikiver, Pinchas Moses, Lisbet [sic] Nilvebrant, and Gunilla Glas are named as inventors of the '600 patent, and that Per Arne Kummelsten and Björn Widén were Swedish patent attorneys who were periodically involved in certain aspects of the prosecution of the application(s) leading to the '600 patent. Pfizer denies the remaining allegations of paragraph 30, including any legal conclusion in those allegations as to whether and during what time any individual had any duty to the United States Patent and Trademark Office under 37 C.F.R. § 1.56

or otherwise, with respect to the filing and prosecution of the application(s) leading to the '600 patent.

31. Pfizer admits that Teva has quoted a passage that appears in section 2001.06(a) of certain editions of the M.P.E.P. Pfizer otherwise denies the allegations of paragraph 31.

32. Pfizer denies the allegations of paragraph 32.

33. Pfizer denies the allegations of paragraph 33.

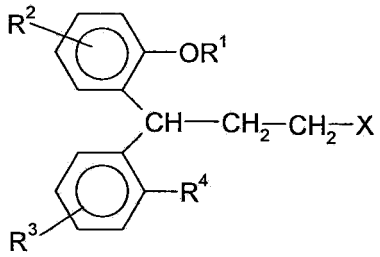
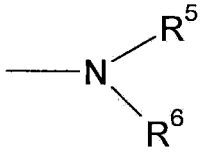
34. Pfizer admits that the '600 patent issued directly from the United States Application Serial No. 07/810,185 (the "U.S. Basic Application"), that the U.S. Basic Application was filed on December 19, 1991, that the U.S. Basic Application was assigned to Kabi Vitrum AB at the time of filing, and that Pharmacia Aktiebolag is the assignee listed on the face of the '600 patent. Pfizer otherwise denies the allegations of paragraph 34.

35. Pfizer admits that the U.S. Basic Application claimed priority to Swedish Patent Application No. 8800207-6 (the "Swedish Basic Application"), that the Swedish Basic Application was filed on January 22, 1988, that the Swedish Basic Application was converted into International Application No. PCT/SE89/00016 (the "Basic PCT") on January 20, 1989, and that the Basic PCT received International Publication No. WO 89/06644 (the "Basic Publication"). Pfizer otherwise denies the allegations of paragraph 35.

36. Pfizer admits that Per Arne Kummelsten and Björn Widén were, for some time on or after the filing date of the Swedish Basic Application, Swedish patent attorneys affiliated with Uppsala Patentbyra. Pfizer also admits that "KUMMELSTEN, Per, Arne et al.; Uppsala Patentbyra" are the listed agents on the Basic Publication. Pfizer denies the remaining allegations of paragraph 36.

37. Pfizer admits that both the U.S. Basic Application and the '600 patent list Nils A. Jönsson, Bengt A. Sparf, Lembit Mikiver, Pinchas Moses, Lisbet [sic] Nilvebrant, and Gunilla Glas as inventors.

38. Pfizer admits that the following is described beginning at line 4 of page 2 of the U.S. Basic Application:

> In the first aspect the invention provides novel 3,3-diphenylpropylamines of formula I
>
> 
> (I)
>
> wherein R^1 signifies hydrogen or methyl, R^2, R^3 and R^4 independently signify hydrogen, methyl, methoxy, hydroxy, carbamoyl, sulphanoyl or halogen, and X represents a tertiary amino group of formula II
>
> 
> (II)
>
> wherein R^5 and R^6 signify non-aromatic hydrocarbol groups, which may be the same or different and which together contain at least three carbon atoms, preferably at least four carbon atoms, especially at least five carbon atoms, and wherein R^5 and R^6 may form a ring together with the amine nitrogen, said ring preferably having no other hetero atom than the amine nitrogen.
>
> The compounds of formula I can form salts with physiologically acceptable acids, organic and inorganic, and the invention comprises the free bases as well as the salts thereof. Examples of such acid addition salts include the hydrochloride, hydrobromide, hydrogen fumarate, and the like.

> When the novel compounds can be in the form of optical isomers, the invention comprises the racemic mixture as well as the individual enantiomers as such.
>
> A preferred sub-class of compounds according to the invention comprises tertiary amines of formula I, wherein each of R^5 and R^6 independently signifies C_{1-8}-alkyl, especially C_{1-6} alkyl, or adamantyl, R^5 and R^6 together comprising at least three, preferably at least four carbon atoms. R^5 and R^6 may carry one or more hydroxy groups, and they may be joined to form a ring together with the amine nitrogen atom.

Pfizer does not otherwise respond to the allegations of paragraph 38, as only conclusions of law are set forth therein.

39. Pfizer admits that, during the prosecution of the U.S. Basic Application, in an Office Action dated July 10, 1992, the examiner stated:

> Claims 1 to 4, 6 and 9 to 15 are rejected under 35 U.S.C. § 103 as being unpatentable over the German, British and U.S. patents and the Chemical Abstracts article cited in the corresponding PCT application. It is requested that copies of the German and British patents be supplied to complete the record.

Pfizer admits that the International Search Report generated in connection with the Basic PCT cited Great Britain Patent Nos. 1,169,944 and 1,169,945, U.S. Patent No. 3,446,901 (the "'901 patent"), and Chemical Abstracts Vol. 97 (1982) abstract 120105N, in addition to other references. Pfizer further admits that no German patents were cited in the International Search Report generated in connection with the Basic PCT. Pfizer otherwise denies the allegations of paragraph 39.

40. Pfizer admits that the applicants provided a copy of Danish Patent No. 111,894 (the "Danish '894 Patent"), cited in the International Search Report generated in connection with the Basic PCT, to the examiner during the prosecution of the U.S. Basic Application. Pfizer further admits that the Danish '894 Patent states that priority was requested from (West) German Patent Application No. K48,245 (the "German Application"), and that reference to the German

Application is made in (West) German Patent No. 1216318 (the "German '318 Patent"). Pfizer denies the remaining allegations of paragraph 40.

41. Pfizer denies the allegations of paragraph 41.

42. Pfizer admits that, during the pendency of the U.S. Basic Application, Swedish Patent Application No. 9203318-2 (the "Swedish Metabolite Application") was filed on November 6, 1992. Pfizer further admits that the Swedish Metabolite Application was converted into International Application No. PCT/SE93/00927 (the "Metabolite PCT") on November 5, 1993. Pfizer otherwise denies the allegations of paragraph 42.

43. Pfizer admits that the specification of the published Metabolite PCT references the Basic Publication. Pfizer denies the remaining allegations of paragraph 43.

44. Pfizer admits that Bengt A. Sparf, Pinchas Moses, and Lisbeth Nilvebrant are listed as inventors on the U.S. Basic Application, the '600 patent, and the Metabolite PCT. Pfizer also admits that "WIDEN, Björn et al.; Kabi Pharmacia AB" are the listed agents on the published Metabolite PCT. Pfizer denies the remaining allegations of paragraph 44.

45. Pfizer admits that an International Search Report, with a date of mailing of February 7, 1994, was generated in connection with the Metabolite PCT, and that it lists the German '318 Patent as a category "X" reference. Pfizer also admits that a category "X" reference is defined in that International Search Report as a "document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone." Pfizer denies the remaining allegations of paragraph 45.

46. Pfizer admits that the International Search Report generated in connection with Metabolite PCT lists the Basic Publication as a category "X" reference. Pfizer denies the remaining allegations of paragraph 46.

47. Pfizer denies the allegations of paragraph 47.

48. Pfizer denies the allegations of paragraph 48.

49. Pfizer admits that the applicants did not provide a copy of the German '318 Patent to the examiner during the prosecution of the U.S. Basic Application. Pfizer denies the remaining allegations of paragraph 49.

50. Pfizer admits that the applicants provided a copy of the Danish '894 Patent, cited in the International Search Report generated in connection with the Basic PCT, to the examiner during the prosecution of the U.S. Basic Application. Pfizer further admits that the Danish '894 Patent states that priority was requested from the German Application, and that reference to the German Application is made in the German '318 Patent. Pfizer denies the remaining allegations of paragraph 50.

51. Pfizer admits that, during the prosecution of the U.S. Basic Application, in an Amendment dated January 11, 1993, the applicants stated:

> In particular, [the Danish '894 Patent] is concerned with a process for preparing certain diphenylalkylamines that have particular effect on the heart and circulation. The particular compounds suggested therein are primary or secondary amines, but do not contain any OH or alkoxy substituent in the ortho position of the phenyl rings.

Pfizer denies the remaining allegations of paragraph 51.

52. Pfizer denies the allegations of paragraph 52.

53. Pfizer admits that both the Danish '894 Patent and Swedish Patent No. 300 822 (the "Swedish '822 Patent") state that priority was requested from the German Application, and

that reference to the German Application is made in the German '318 Patent. Pfizer denies the remaining allegations of paragraph 53.

54. Pfizer admits that, during the prosecution of the U.S. Basic Application, in an Amendment dated January 11, 1993, the applicants stated:

> In particular, [the Danish '894 Patent] is concerned with a process for preparing certain diphenylalkylamines that have particular effect on the heart and circulation. The particular compounds suggested therein are primary or secondary amines, but do not contain any OH or alkoxy substituent in the ortho position of the phenyl rings.

Pfizer denies the remaining allegations of paragraph 54.

55. Pfizer denies the allegations of paragraph 55.

56. Pfizer denies the allegations of paragraph 56.

57. Pfizer denies the allegations of paragraph 57.

58. Pfizer denies the allegations of paragraph 58.

59. Pfizer admits that, during the prosecution of the U.S. Basic Application, the examiner cited the '901 patent as a basis for rejecting certain then-pending claims. Pfizer admits that, during the prosecution of the U.S. Basic Application, in an Office Action dated July 10, 1992, the examiner stated:

> Claims 1 to 4, 6 and 9 to 15 are rejected under 35 U.S.C. § 103 as being unpatentable over the German, British and U.S. patents and the Chemical Abstracts article cited in the corresponding PCT application. It is requested that copies of the German and British patents be supplied to complete the record. These references disclose structurally related products. Selection from within a genus is held within the skill of the worker in the art absent a show of unexpected properties.

Pfizer also admits that, during the prosecution of the U.S. Basic Application, in an Office Action dated February 27, 1993, the examiner stated:

> Claims 1-4, 6, 9, 10, and 16 are rejected under 35 U.S.C. 103 as being obvious over Jones of record. The British patents of record have been dropped as being cumulative and the Danish patent and Vol. 97 Chemical

> Abstracts article have been overcome by applicants' arguments. Jones generically teaches the present compounds and specifically discloses the dimethylamino lower homolog. Applicants' showing in the specification has been considered but is not seen convincing because the closest compound of the present claims containing three carbon atoms (ethylmethylamino) has not been compared. Further, the significance of the data is not seen.

Pfizer denies the remaining allegations of paragraph 59.

60. Pfizer denies the allegations of paragraph 60.

61. Pfizer denies the allegations of paragraph 61.

62. Pfizer admits that, during the prosecution of the U.S. Basic Application, in a Response dated September 1, 1993, the applicants stated:

> [I]n general, the tests, including the table on page 43 ff, clearly shows [sic] that the claimed compounds have improved selectivity between the desired anticholinergic effect and undesired side effects.
>
> Since Jones is not concerned with anticholinergic agents, the selection of substituents to arrive at the compounds of the present invention would merely be fortuitous without any reasonable degree of expectation that the properties achieved by the present invention would be obtained. Furthermore, Jones is even more remote with respect to compounds reciting 'at least four carbon atoms.'

Pfizer denies the remaining allegations of paragraph 62.

63. Pfizer denies the allegations of paragraph 63.

64. Pfizer denies the allegations of paragraph 64.

65. Pfizer denies the allegations of paragraph 65.

66. Pfizer denies the allegations of paragraph 66.

67. Pfizer admits that, during the prosecution of the applications that led to the '600 patent, the applicants submitted "test results" for "compounds according to the invention," and "for comparison purposes," for N,N-dimethyl-3-(2-methoxyphenyl)-3-phenylpropylamine, a compound disclosed in the '901 patent. Pfizer also admits that, during the prosecution of the

U.S. Basic Application, in a Response dated September 1, 1993, the applicants stated that "the specification includes a comparison of the claimed invention and the N,N-dimethyl-3-(2-methoxy phenyl)-3-phenylpropyl amine, which is considered to be the closest prior art compound that has been fabricated." Pfizer further admits that, during the prosecution of the U.S. Basic Application, in a Response dated April 22, 1994, the applicants amended one of the then-pending claims to require that "R^5 and R^6 together contain at least four carbon atoms." Pfizer denies the remaining allegations of paragraph 67.

68. Pfizer denies the allegations of paragraph 68.

69. Pfizer denies the allegations of paragraph 69.

70. Pfizer admits that, during the prosecution of the applications that led to the '600 patent, the applicants submitted "test results" for "compounds according to the invention," and "for comparison purposes," for N,N-dimethyl-3-(2-methoxyphenyl)-3-phenylpropylamine, a compound disclosed in the '901 patent. Pfizer also admits that, during the prosecution of the U.S. Basic Application, in a Response dated April 22, 1994, the applicants stated:

> [A]dditional comparative tests have been conducted in which the following two compounds according to the invention – in which R^5 plus R^6 contain four carbon atoms – have been compared with the dimethylamino compound according to Jones…
>
> The first compound (A) is a 2-methoxyphenyl compound and the second compound (B) is a 2-hydroxyphenyl compound. The compound (B) has an IC_{50} for anticholinergic effect of 180 nmoles and the compound (A) has an IC_{50} for anticholinergic effect of 220 nmoles. This means that compound [sic] (A) and (B) are approximately seven times better than the compound according to Jones (see the Table on page 43 in the present application).

Pfizer denies the remaining allegations of paragraph 70.

71. Pfizer denies the allegations of paragraph 71.

72. Pfizer denies the allegations of paragraph 72.

73. Pfizer denies the allegations of paragraph 73.

74. Pfizer denies the allegations of paragraph 74.

75. Pfizer admits that, during the prosecution of the U.S. Basic Application, the applicants submitted a declaration under 37 C.F.R. § 1.132 of inventor Dr. Lisbeth Nilvebrant, dated June 23, 1994 (the "Nilvebrant Declaration"). Pfizer denies the remaining allegations of paragraph 75.

76. Pfizer admits that the Nilvebrant Declaration stated, in part:

> The comparative tests reported in Exhibit A attached to this declaration were conducted by me and/or under my direction and supervision.
>
> The results reported in Exhibit A are the values that were obtained from the comparative tests. These tests establish that the compounds (A) and (B) that were tested are approximately six to seven times better than the compound according to Jones, with respect to anticholinergic activity (see tables on page 43 of the above application).

Pfizer denies the remaining allegations of paragraph 76.

77. Pfizer denies the allegations of paragraph 77.

78. Pfizer denies the allegations of paragraph 78.

79. Pfizer denies the allegations of paragraph 79.

80. Pfizer denies the allegations of paragraph 80.

81. Pfizer denies the allegations of paragraph numbered as "28," immediately following paragraph 80.

82. Pfizer denies the allegations of paragraph 81.

* * *

Pfizer denies that Teva is entitled to the relief sought in items (A-J) on page 40 of their Counterclaims.

AFFIRMATIVE DEFENSES TO COUNTERCLAIMS

1. Counterclaim-Defendants Pfizer Inc., Pharmacia & Upjohn Company LLC, and Pfizer Health AB (collectively, "Pfizer") hereby reallege and incorporate by reference the allegations set forth in the Complaint in this action.

2. U.S. Patent No. 5,382,600 (the "'600 patent") is valid.

3. U.S. Patent No. 6,630,162 (the "'162 patent") is valid.

4. U.S. Patent No. 6,770,295 (the "'295 patent") is valid.

5. Teva Pharmaceuticals USA, Inc.'s ("Teva") importation, sale or offer for sale of Teva's generic tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, and the administration of those products within the United States will infringe the claims of the '162 patent.

6. Teva's importation, sale or offer for sale of Teva's generic tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, and the administration of those products within the United States will infringe the claims of the '295 patent.

7. Teva's importation, sale or offer for sale of Teva's generic tolterodine tartrate extended release capsules, in 2 and 4 mg dosages, and the administration of those products within the United States will infringe the claims of the '600 patent.

8. The '600 patent is enforceable.

9. Teva's Counterclaims are barred, in whole or in part, because they fail to state a claim upon which relief may be granted.

10. The Court lacks subject matter jurisdiction over Teva's Counterclaims, as pled.

Dated: January 23, 2008
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